UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,127	10/10/2001	Eitan T. Wiener	2640/1G820-US1	1298

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PANTUCK, BRADFORD C

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

	Application No.	Applicant(s)
Office Action Summary	09/975,127	WIENER ET AL.
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on _October 4, 2004_.

2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
   closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) _1-46_ is/are pending in the application.

     4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) _1-13,16-21,23-34,37-40 and 43-46_ is/are rejected.

7) ☒ Claim(s) _14, 15, 22, 35, 36, 41, 42_ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

     a) ☐ All   b) ☐ Some * c) ☐ None of:

       1. ☐ Certified copies of the priority documents have been received.

       2. ☐ Certified copies of the priority documents have been received in Application No. _____.

       3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage
         application from the International Bureau (PCT Rule 17.2(a)).

     * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
     Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
     Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1.   Claims 1-12, 17, 21, 24-32, 34, 38-40, and 44-46 are rejected under 35

U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,017,354 to Culp et al. Culp

discloses a system for implementing surgical procedures (30) according to the

claimed invention. Culp also discloses a method for implementing surgical

procedures in a system (30) according to the claimed invention. Culp's system

includes an ultrasonic surgical hand piece (33), which has a sheath (50) [see Fig. 2]

with an end-effector. The end-effector is a blade, referred to as a "saw" (35) in

Column 5, lines 37-38 [see Fig. 1].

Note: An important aspect of Culp's disclosure that the applicant should

understand relates to Culp's disclosure of an *ultrasonic surgical hand piece*. First of

all, in the BACKGROUND OF THE INVENTION, Culp expresses that the reason

for his invention—the problem to be solved—is that with all of the modern surgical

tools now available it is expensive to keep separate generator consoles for each one

[Column 1, lines 50-58]. He is setting out to provide a single integrated console that

is able to accept tools having many different power and controls requirements [Column 3, lines 44-51] that will save time for surgical staff.

He claims his invention broadly, but explains in the Specification that his invention is meant to encompass power tools of many types, including micro drills [Column 1, lines 44-49], power tools with integrated light and water sources [Column 2, lines 45-55], surgical lasers, and finally, *ultrasonic scalpels* [Column 3, lines 35-45]. Culp further discloses the use of an ultrasonic tool/hand piece in Column 24, lines 37-40 and in Column 57, lines 53-56. In summary, Culp discloses the use of both ultrasonic and non-ultrasonic surgical hand pieces for use with a console.

Culp's system also includes a generator console (36) for controlling the hand piece. The console (36) sends a drive current to drive the hand piece [Column 5, lines 38-41]. When an ultrasonic scalpel is used with this generator console [Culp discloses the use of both ultrasonic and non-ultrasonic surgical hand pieces] this *drive current will inherently impart ultrasonic longitudinal movement to the blade.*

Next, Culp discloses a memory disposed in the sheath (50) of the end-effector. The sheath (50) could also be called a "grip" or a "handle," as in Claim 2, because the hand piece is held with the user's hand. Memories 72 and 74 are fitted inside of the sheath (50) of the end-effector [see Column 6, lines 51-52; Figures 2 and 3]. The console reads information [see Column 6, line 65 – Column 7, line 1] stored in the memory (72 and 74) to determine whether or not a data string is present. For example, the console reads the memory 72 to check the serial number of the hand

piece [Column 15, lines 40-57. The hand piece can be authenticated for use if the data string (correct serial number, for example) is present.

Regarding the limitation, "said end-effector being connectable to said hand piece," Culp discloses "burr 34" (for example), *"coupled to handpiece 32"* [emphasis added: Column 5, lines 35-36]. Thus, Culp discloses an end effector connected to a hand piece.

Regarding the limitation, "periodically querying the memory during the ultrasonic movement of the end-effector to adjust operation of the console" [claim 32] Culp discloses periodically querying, for example, the motor speed, and having the information pass through memory (72) [see Column 48, lines 50-58]. The current sense circuit *must be* regularly, i.e. periodically, checking the motor speed if an average motor speed for the operation can be generated. Additionally, almost all of Culp's request for information commands that happen within his device are *feedback loops* [see for example Fig. 23], which inherently periodically check for variances (in motor speed, temperature of end-effector, etc...) in order to have an up-to-the-moment read on the current state of the surgical device.

2.   Regarding Claims 1, 4, 5, and 45 Culp discloses a system with all of the limitations of the claims, including a data string, which is stored in the memory [see above]. The fact that the applicant's data string is *copyrighted* does not add any structural limitations on the data. For example, whether or not the string of numbers "57896768932775579" is copyrighted or not *does not change the value* of the

numbers in the string. Consequently, the term "copyrighted," additionally found in

Claims 32 is not considered to add any structural limitation to the invention.

3.   Regarding Claim 9, Culp discloses a system for implementing surgical

procedures, including a hand piece, a generator console, and a memory, as described

above. Additionally, Culp's console writes historical usage and diagnostic

information and configuration information into the memory. For example, the

console writes the duration of activation of the hand piece into field 466 of the

memory. This information can be used to diagnose the need for maintenance of the

hand piece [Column 20, line 56 to Column 21 line 13]. Note that Figures 13 and 14

are block diagrams showing the data field in the read/write memory contained within

the hand piece [see Column 4, lines 35-42].

4.   Regarding Claims 10 and 12, Culp discloses a system for implementing surgical

procedures, including a console that reads information stored in the memory [see

above] and displays the information [Column 5, lines 42-48] and an interpretation of

the information on the console display (37). An example of the screen displaying an

interpretation of information given in the memory is found in Column 17, lines 15-40.

The data (coefficients a, b, and c) is stored in the memory, and the data is interpreted

using the equation shown in line 25 to output "y" on the display (37) of the console.

        Further regarding Claims 10 and 12, Culp discloses a generator console, which

includes a digital signal processor (518). The digital signal processor

[microprocessor] exchanges digital signals with the memory of the hand piece [see

Column 23, lines 40-48].

5.   Regarding Claims 2, 6-8, 11, 21, 34, and 46, Culp discloses a system and a
method for implementing surgical procedures, including all of the limitations of the
claims, including an alarm/handicap mode and a disabling function. The console
instructs the hand piece to operate in alarm/handicap mode by displaying a warning
statement or sounding an audio warning tone and reducing the power. The console
can then disable the hand piece if the temperature of the hand piece exceeds the
disable limit [Column 54, lines 27-40; Column 51, lines 8-13].

6.   Regarding Claim 17, Culp discloses that the memory in his device can be used
with a hand piece that is a cauterizing tool [Column 57, 12-17].

7.   Regarding Claim 24, *no physical structure is added to the invention by this
claim by describing a method of using the invention.* The memory in the system
records a handicap limit and a disable limit [see above #11].

8.   Regarding Claims 25 and 38, Culp discloses a system and a method meeting all of
the limitations of the respective claims in which the handicap limit and the disable
limit are reinitialized based on varied operational conditions of the hand piece. Table
1 [Column 16] shows that the handicap and disable limits are stored in the memory,
and Culp says that this memory is read each time the hand piece is initially
configured [Column 6, line 51-Column 7, line 1]. Culp says that the user can vary the
maximum speed at which the internal motor of the hand piece can operate, i.e. an
"operational condition" of the hand piece [Column 16, line 66 to Column 17 line 14
and that this will reinitialize the data stored in the memory of the hand piece. The

data stored in the hand piece affects the handicap limit and the disable limit [see Table 1].

9.   Regarding Claims 26 and 39, the console is programmed by reading a reprogram code stored in the memory of the hand piece, and the console is upgraded by reading a code stored in the memory [Column 6, line 65-Column 7, line 1]. The data stored in the EEPROM is considered to be a code that upgrades and reprograms the console. The console determines whether or not codes are needed at various times: for example, if a new high temperature has been reached by the hand piece, then the console is reprogrammed with that information [Column 21, lines 14-27].

Further regarding Claim 26, *no physical structure is added to the invention by this claim by describing a method of using/programming the invention.*

10.   Regarding Claim 27, *no physical structure is added to the invention by this claim by describing a method of using/programming the invention.* Furthermore, if it is determined that a reprogram of the console is *not needed,* then a non-hand piece device that plugs into the hand piece (with an associated memory) *is not needed.*

11.   Regarding Claims 28 and 40, Culp discloses a system [and a method for using that system], which has information stored in the memory that correlates to energy level information and corresponding output displacement. The console reads the energy level information (based on the speed) and drives the hand piece according to the corresponding output displacement [see Column 47, lines 12-39; Fig. 28]. Additionally, information regarding the amount of current the motor should draw [Column 18, lines 17-22], the torque of the motor [Column 18, lines 53-55], and the

maximum rate the motor should accelerate [Column 19, lines 50-55] are all different

types of energy level information stored that correlate to output displacement.

Further regarding Claim 28, *no physical structure is added to the invention by this*

claim by describing a method of using/programming the invention.

12.   Regarding Claims 29 and 30, Culp discloses the system, as claimed, which stores

information in the memory. No additional *structure* is added to the invention by

describing what kind of information is stored in the memory.

13.   Regarding Claim 31, the claim is taken to be a Markush claim, in which any one

of the claimed aspects meets the claim. Culp discloses a memory that consists of an

Electrically Erasable Programmable Read Only Memory, a Read Only Memory, an

Erasable Programmable Read Only Memory, a Random Access Memory [Column 6,

line 51 – Column 7 line 5], a Programmable Logic Array [Column 28, lines 12-19], -

and a microprocessor [see above].

14.   Further, with regards to Claims 1-3, 9, 10, 12, 32, and 44, Culp discloses a

memory disposed in the sheath of an end effector, which optimizes operation of the

generator console for operation with the end effector to achieve optimal tissue effects

with the end effector, as claimed by the Applicant. Anything that affects the

performance of the device will affect its response to/interaction with tissue. The

memory of Culp's device stores data, as previously expounded, and is able to store

data associated with the nature of the tissue to be cut with the scalpel. The memory

of Culp's device is also able to store performance criteria such as energy level

information. This information would help the generator console [and ultimately, the surgeon] *optimize the results of the tissue cutting surgery.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18, 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,017,354 to Culp et al. in view of U.S. Patent No. 5,400,267 to Denen et al.

15.   Regarding Claim 18, Culp discloses the system as claimed, but fails to explicitly disclose a memory that blocks the use of incompatible hand pieces. However, Denen discloses a memory located in an electric surgical device (scalpel) for use with a console that automatically establishes the compatibility of the scalpel (hand piece). If the hand piece is incompatible with the console, its use is blocked [Column 2, lines 36-45]. The disclosed reason for supplying this memory, which automatically verifies compatibility of the hand piece with the console, is so that damage is not done to equipment when incompatible hand pieces are inadvertently connected to consoles [Column 2, lines 16-27]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use a memory with an

electrical scalpel, as taught by Denen, in order to ensure damage is not done to the

equipment by accidentally using a hand piece that is incompatible with a console.

16.   Regarding Claim 19, Culp discloses the device as claimed, but fails to explicitly

disclose a hand piece that is authenticated for use with the console using cyclical

redundancy check. However, Denen discloses an electric surgical device (scalpel)

that is authenticated for use by a console using cyclic redundancy check. It uses CRC

to ensure that the console reads the authentication information stored in the hand

piece without error [Column 16, line 65 to Column 17, line 19]. Therefore, it would

have been obvious to one having ordinary skill in the art at the time of the invention

to employ cyclical redundancy check in an electric scalpel in order to make sure of

the accuracy of the message sent from the hand piece to the console.

17.   Regarding Claim 23, Culp fails to disclose a system in which there is a time limit

for the use of the hand piece. However, Denen teaches that an electrical scalpel

system ought to have a memory [see Figures 1 and 8] that stores a handicap limit

[Column 13, lines 48-53] and a disable limit [Column 13. lines 41-48] that limit the

length of time a hand piece can be used [Column 10, lines 42-45]. Denen's hand

piece thus operates in handicap mode if the time the hand piece has been active

exceeds the handicap limit, and the console disables the hand piece if the time the

hand piece has been active exceeds the disable limit.

Culp's motivation for providing this handicap/disable feature is so that the

surgeon can make sure that he or she replaces the hand piece before it fails, especially

in critical medical applications [Column 1, lines 40-44]. Therefore, it would have

been obvious to one of ordinary skill in the art at the time of the invention to provide

a handicap mode and a disable limit for the hand piece to ensure that the user replaces

the hand piece before it fails, while performing critical surgeries.

18.   Claims 20, 24, 37, and 43 are rejected under 35 U.S.C. 103(a) as being

unpatentable over U.S. Patent No. 6,017,354 to Culp et al. in view of U.S. Patent No.

6,331,181 to Tierney et al. Culp discloses the system according to Claim 20 and the

method according to Claim 33, but does not explicitly disclose that the data string is

an encrypted code, or that the hand piece is authenticated for use by decoding an

encryption algorithm. However, Tierney teaches that one would use encryption

algorithm to authenticate the use of a hand tool with a console so that the test would

not have to be done by hand. The algorithm automates the authentication process

[Column 17, lines 22-42].

Tierney discloses a data string that is an encrypted code, and the hand piece is

authenticated for use with the console by decoding a corresponding encryption

algorithm in the console and provides a responding data pattern [Column 17, lines 22-

42; see Fig. 15]. Therefore, it would have been obvious to one having ordinary skill

in the art at the time of the invention to authenticate a hand piece by means of an

encrypted data string and an encryption algorithm, as taught by Teirney, in order to

automate the process of authenticating the tool.

Regarding Claims 24 and 37, Culp discloses the method according to

Claim 32 but does not disclose a means for keeping track of the number of activations

for the hand piece within a time period. However, Tierney discloses a means for

keeping track of the number activations for the hand piece within a time period

[Column 18, Claim 14] for the purpose of disabling the hand piece, and states that

one would employ a means to keep track of the number of activations in a given time

period so that one would not need to do it by hand (resorting to an external table)

[Column 2, lines 54-65] and so as to increase the safety of using an electronic hand

piece [Column 2, lines 30-36].   Therefore, it would have been obvious to one having

ordinary skill in the art at the time of the invention to employ a means to keep track of

the number of activations in a given time period for the purpose of disabling the hand

piece, as taught by Teirney, in order to automate the process of recording the rate of

activation and to increase the safety of using electrical hand pieces.

19.   Regarding Claim 43, Culp discloses the method according to Claim 32 but does

not disclose a means for keeping track of the number of uses of the end-effecter.

However, Tierney discloses a means for keeping track of the number of uses for the

end-effecter and a means for keeping track of a number of remaining uses allowed for

the end-effecter [Column 2, lines 54-65]. The *number of remaining uses* are

considered to be included under "tool life data," because Tierney teaches broadly

about many kinds of tool life data, including many characteristics of the end-effecter

[Column 15, line 59-Column 16 line 19].

20.   Claims 20 and 33 are also rejected under 35 U.S.C. 103(a) as being unpatentable

over U.S. Patent No. 6,017,354 to Culp et al. in view U.S. Patent No. 6,298,255 to

Cordero et al. Culp discloses the system according to Claim 20 and the method

according to Claim 33, but does not explicitly disclose that the data string is an

encrypted code, or that the hand piece is authenticated for use by decoding an

encryption algorithm. However, Cordero teaches that one would want to use

encryption with a hand piece/console system so as to protect the console from being

used with a counterfeit hand piece [Column 3, lines 32-37]. Figure 16 shows the

authentication process, including decoding a corresponding encryption algorithm in

the console and providing a responding data pattern (926). Therefore, it would have

been obvious to one having ordinary skill in the art at the time of the invention to

authenticate a hand piece by means of an encrypted data string and an encryption

algorithm, as taught by Cordero, to protect the console from being used with a

counterfeit hand piece.

21.   Claims 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over

U.S. Patent No. 6,017,354 to Culp et al. in view U.S. Patent No. 6,434,507 to Clayton

et al. Culp discloses the invention as claimed, and as described above, but fails to

disclose a memory communicating electrically with a switch adaptor through direct

contacts. However, Clayton (among others) teaches that one would use direct

contacts with memory that communicates electrically with a switch adaptor with high

speed hand piece/controller assembly so as to make sure that no information is lost

when the end-effector is changed by the user [Column 1, lines 56-63]. Figure 6

shows the circuitry involved, and the direct contacts specifically. Using direct

contacts for this purpose is well known in the art of ultrasonic hand pieces.

Therefore, it would have been obvious to one having ordinary skill in the art at the

time of the invention to employ direct contacts to connect the memory [end-effector]

to the switch adaptor of Culp's device in order to make sure that information is maintained accurately despite the changing of end-effectors by various users [Column 2, lines 30-35], as taught by Clayton.

Allowable Subject Matter

22.   Claim 14, 15, 22, 35, 36, 41, and 42 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

23.   Applicant's arguments filed October 4, 2004 have been fully considered but they are not persuasive. Independent claim 1 does not prevent the sheath of the hand piece ["an ultrasonic surgical hand piece having an end-effector with a sheath] from being the same component as the sheath of the end-effector ["a memory disposed in the sheath of the end-effector"]. Yes, Culp refers to component 50 as the "motor housing" [Column 7, lines 64-65], and in this capacity, it is acting as a sheath of the hand piece. However, sheath 50 also acts as a "sheath of the end-effector" in that *component 50 houses at least a portion of the end effector 34.* In Column 6, lines 42-50, Culp describes how the "burr 34 or other cutting accessory" is secured to rotor 56, which is a distal part of the sheath 50. In this sense, component 50 is a sheath *of* [i.e., related to, associated with] the end-effector. Applicant has not claimed

Regarding Claim 2, Examiner would like to discuss "a memory disposed in a portion of the end-effector selected from the group consisting of a grip, handle and

mounting," as claimed by the Applicant. Applicant argues that the memory claimed

is in the end-effector (page 20, line 6), however, the Applicant is apparently *including*

the grip, handle, and mounting as parts of the end-effector. The term "hand piece",

as generally referred to in the art is the part of the instrument that one grips—it is the

"handle" of the equipment that the surgeon holds. Culp discloses a memory located

inside of the grip/handle 50. Applicant does not claim a memory located on the

surface of the end-effector itself (i.e., on the blade of the cutting knife, or on the drill

bit). In the specification, page 20, line 18—page 21 line 3 explains what is meant by

a memory located on the grip, handle or mounting part, with respect to Figure 4B.

Examiner contends that these locations are not, by any generally accepted definition,

part of the end-effector of the device. Rather, these memories are a part of the hand

piece of the device.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Bradford C Pantuck whose telephone number is (571)

272-4701. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

number for the organization where this application or proceeding is assigned is 703-

872-9306.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

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BCP
December 15, 2004

ANHTUAN T. NGUYEN
PRIMARY EXAMINER
12/22/04